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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,596	12/26/2001	Andreas Pluckthun	VOS-25	8037

26633 7590 06/23/2004

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EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,596	PLUCKTHUN ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION : *Election/Restriction (e.g. Lack of Unity)*

Status of the Claims

Claims 1-22 are currently pending.

The following prior art cited in the PCT/EPOO/05922 search report to which the present application claims priority will be referred to below:

D1: O'SHEA ET AL:CURRENT SCIENCE,, vol. 3. no.10 1993, pp.658-667.

D2: YU ET AL: BIOPHYSICAL CHEMISTRY vol. 59, 6 April 1996, pp.299-314.

D3: HODGES: BIOCHEM. & CELL BIOL.BIOCHIM. vol. 74, no. 2, 1996,pp 133-154.

D4: ARNDT ET AL: FASEB JOURN. vol. 11 no. 9. 1997, page A1327 17th Int'l Congress of Biochem.& Mol. Biol. in conjunction wlth the Annual Mtg of the Amer. Soc. of Biochem.& Mol. Biol. San Francisco, Cal. Aug 24-29, 1997.

D5: WO 98 34120 A (PELLIETIER) August 1998.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. The inventions are listed as the following Groups I-XVI:

I. Claim 5 and 22(in part), drawn to "A" peptides A1-A11 and kit.

II. Claim 6 and 22 (in part), drawn to "B" peptides B1-B11 and kit.

III.. Claim 8 and 22 (in part), drawn to an "optimized" polypeptide comprising one or more of "A" peptides and one or more of "B" peptides and kit.

IV. Claim 9, drawn to a composition comprising an "A" and "B" peptide.

V. Claims 10-11(in part) and 22 (in part), drawn to a complex/conjugate/fusion of a "further (poly)peptide/protein" and an "A" peptide and kit.

VI. Claims 10-11 (in part) and 22 (in part), drawn to a complex/conjugate/fusion of a "further (poly)peptide/protein" and an "B" peptide and kit.

VII. Claims 10-11(in part) and 22 (in part), drawn to a complex/conjugate/fusion of a "further (poly)peptide/protein" and an "optimized polypeptide"comprising one or more of "A" peptides and one or more of "B" peptides and kit.

VIII. Claims 12 and 20-22(in part), drawn to "multimeric" complex/conjugate/fusion of a "further (poly)peptide/protein" and an "A" and/or "B" peptide and a composition (pharmaceutical/diagnostic) and kit.

IX. Claims 13-19 (in part), drawn to a DNA encoding an "A" peptide, a host cell and vector comprising the DNA and a recombinant method of making.

X. Claims 13-19 (in part), drawn to a DNA encoding an "B" peptide, a host cell and vector comprising the DNA and a recombinant method of making.

XI Claims 13-19 (in part) , drawn to a DNA encoding an "optimized" polypeptide comprising one or more of "A" peptides and one or more of "B" peptides, a host cell and vector comprising the DNA and a recombinant method of making.

XII. Claims 13-19 (in part), drawn to DNA encoding a complex/conjugate/fusion of a "further (poly)peptide/protein" and an "A" peptide, a host cell and vector comprising the DNA and a recombinant method of making.

XIII. Claims 13-19 (in part), drawn to a DNA encoding a complex/conjugate/fusion of a "further (poly)peptide/protein" and an "B" peptide, a host cell and vector comprising the DNA and a recombinant method of making.

XIV. Claims 13-19 (in part), drawn to a DNA encoding a complex/conjugate/fusion of a "further (poly)peptide/protein" and an "optimized polypeptide"comprising one or more of "A" peptides and one or more of "B" peptides, a host cell and a vector comprising the DNA and a recombinant method of making.

XV. Claims 13-19 (in part), drawn to a DNA encoding a "multimeric" complex/conjugate/fusion of a further (poly)peptide/protein" and an "optimized polypeptide"comprising one or more of "A" peptides and one or more of "B" peptides, a host cell and a vector comprising the DNA and a recombinant method of making.

XVI. Claims 1-4 and 7 ("use" claim), drawn to a combinatorial method for identifying heteroassociating "A" and "B" peptides.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The above claims address heteroassociating polypeptides. However, heteroassociating polypeptides are known in the art as described in references D1-D3 recited above. For example, reference D1 teaches the design of peptides based on studies of fos/jun and gcn4 leucine zippers which form stable, helical heterodimers. The availability of many heteroassociating sequences in the prior art (references D1-D3) shows that the skilled person would be motivated to find other possible heteroassociating sequences derivable from fos/jun leucine zipper or any other known coiled-coil forming pair. Therefore, for new peptides obtained by said approach, a special technical feature must be evident in order for there to be an inventive step. Claims 1-4,7 concern a method for identification of a hetero-associating polypeptides by combining two peptide libraries and selecting for a property caused by the heteroassociation, such method being taught by the closest prior art (reference D4) which teaches in vivo screening of interactive peptide libraries of potential coiled-coil forming peptides formed by randomizing at the e and g positions of the heptad; including reference libraries (e.g. 1 and 2) which contain peptides (individually and in combination) within the scope of the presently claimed libraries "A" and "B" , respectively. Accordingly, as set forth above, said claimed heteroassociating peptides are not considered inventive and cannot establish novelty and/or inventive step of the method which is known as such.

Additionally, it is noted that Inventions I-VIII are drawn to different compounds having different chemical structure and/or different physicochemical properties, which are capable of separate manufacture and/or use and which require separate and/or divergent manual/computer structure, bibliographic patent and non-patent literature searches which are separately and individually burdensome.

Further, the compounds (e.g. peptides, fusions, compositions, DNA) lack unity of invention since these compounds lack a common core structure that would be necessary to elicit a common activity and as such constitute improper Markush groups. See MPEP: Annex B "Unity of Invention Part 1 Instructions Concerning Unity of Invention: "(f) Markush Practice". For example, the "A" peptides differ from the "B" peptides in amino acid sequence and/or length and fail to share a common core (e.g. fixed amino acids) necessary to elicit a common property. Further, the addition of "further" peptidic structure (e.g. "further polypeptide/protein) structure in the nature of fusion/conjugates with any monomeric or polymer "A" or "B" peptides in an structural relationship formulate new and distinctly different compounds. Finally, DNA is totally unrelated in structure, function etc. as compared to (fusion/complex or individual) peptides. Additionally, DNA encoding different peptides/proteins or conjugates would necessarily possess different sequences and length

Still further, Inventions IX-XV lack unity of invention since these individual groups utilize distinctly different DNA sequences(or host cells that contain these sequences) (e.g. different core structure) in distinctly different recombinant methods

due to methods which differ in objective (e.g. syntheses of distinctly different proteins) and/or the use of distinctly different (e.g. different core structure) DNA sequences.

It is further noted that the above inventions would require different and independently burdensome manual/computer patent and non-patent literature searches.

ELECTION OF SPECIES

(GROUPS I, II, V &VI) and (GROUPS III, IV, VII & VIII ABOVE)

1. This application contains claims directed to the following patentably distinct species of the claimed invention: "A" peptides (Group I), "B" peptides (Group II) or combinations thereof (e.g. Groups III or IV).

These Groups encompass peptides which are drawn to independent and/or distinctly different compounds having different chemical structure and/or different physicochemical properties, which are capable of separate manufacture and/or use and which require separate and/or divergent manual/computer structure, bibliographic patent and non-patent literature searches which are separately and individually burdensome.

Applicant is required under 35 U.S.C. 121 to elect:

I) a single disclosed species of "A" or "B" for Groups I, V OR VI); OR

II) a"single A" and a "single B" compound for groups III, IV, VII or VIII above

if elected for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

2. **FURTHER LACK OF UNITY and Election of Species under 35 USC 121 (GROUPS V-VIII)**

These Groups encompass compositions comprising a "further (poly)peptide/protein" which lacks any fixed structure or common core necessary to elicit a common activity (e.g. improper Markush group) and would encompass a potentially infinite number of "(poly)peptide/proteins" of diverse chemical structure and/or different physicochemical properties, which are capable of separate manufacture and/or use and which require separate and/or divergent manual/computer structure, bibliographic patent and non-patent literature searches which are separately and individually burdensome.

Applicant is required to elect:

I. A SINGLE CLASS OF COMPOUNDS (E.G. see Markush listing of Claim 11)

AND

ii. Applicant must then elect a SINGLE COMPOUND FROM within the elected class of compound, and provide a structural formula corresponding thereto.

for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

It is noted that the above elections relating carry over to the corresponding DNA claims (e.g. of Groups IX-XV).

3. ***ELECTION OF SPECIES (FOR XVI ONLY)***

This application contains claims directed to the following patentably distinct species of the claimed invention: different "screenable of selectable properties which result in different and independently and/or distinctly different methods with different objectives, reaction conditions and different final products.

Applicant is required under 35 U.S.C. 121 to elect a single "screenable or selectable property" for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable

Applicant is advised that a reply to all of the above requirements must include an identification of the species that is elected consonant with these requirements, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

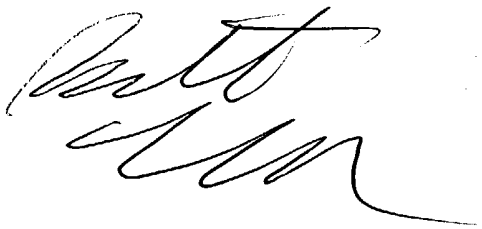
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639



BC
June 17, 2004